UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

Office Use Only Protocol Number:

AMENDMENT REQUEST FORM

This form is to be submitted with amendments to previously approved protocols. Revised procedures should not be implemented until ethics approval has been received.

1. TITLE OF RESEARCH PROJECT

Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures

U of T Protocol reference number: #20362
Date of most recent approval:June 25, 2007 for next expiry date of June 24, 2008

2. INVESTIGATOR INFORMATION

Investigator:

Title: Dr.	Name: Frances Silverman	
Department: Gage Occupational and Environmental Health Unit		
Mailing address: 223 College St. Toronto, ON M5T 1R4		
Phone: (416) 978-5883	Fax: (416) 978-2608	Email: frances.silverman@utoronto.ca

Faculty Supervisor/Sponsor:

Title:	Name:	Personnel Number:
Department:		
Mailing address:		
Phone:	Fax:	Email:

3. LOCATION(S) WHERE THE RESEARCH WILL BE CONDUCTED:

University of Toronto ☒
Hospital ☐ I specify site(s)
School board or community agency ☐ specify site(s)
Community within the GTA ☐ specify site(s)
International ☐ specify site(s)
Other ☐ specify site(s)

The University of Toronto has recently reached an agreement with the University-Affiliated Teaching Hospitals, regarding ethics review of hospital-based research. Based on this agreement, certain hospital-based research is now exempt from ethics review at the University of Toronto. If your research is based at a University-Affiliated Teaching Hospital please consult the following document to determine whether or not your research requires review at the University of Toronto http://www.research.utoronto.ca/ethics/eh_where_tahsn.html.

3. PROPOSED CHANGES

a) Please describe the proposed study amendment or modification in the space provided below. A copy of the complete protocol with the changes indicated in bold text should be submitted with this form. Please specify if it is a **minor** (e.g. administrative change) or **major** (e.g. addition of study method) change.

Approval is requested for the following minor amendments:
After discussion and exchange with our collaborators at Harvard and the funding agency – the US EPA, we have added some points of clarification. We stated in the cover letter of an amendment to St. Michael's Hospital REB and in our initial expedited application (May 9, 2007) to your board that we were requesting "An increase in the exposure concentration of coarse particles (from 150 to 400 µg/m3) and fine particles (from 150 to 500 µg/m3). These would be maximum levels that we would not go above." The point that these were indeed maximum levels was not clear, and furthermore we did not specify the actual target levels over the 2-hour exposure. The target levels would be 50% of the maximums and both the target and maximums are levels similar to those used by other researchers in the U.S. doing similar types of controlled human exposure studies with coarse and fine particles without adverse subject reactions.

As well we would like to make an addition to the protocol to add collection of urine samples pre, post and 24 hours post exposure for measurements of oxidative stress.
The attached revised protocol and consent forms have been amended to reflect these changes.

These amendments are also being submitted to St. Michael's Hospital REB.

b) Will the proposed amendment change the overall purpose or objective of the study?

☐ Yes ☒ No

If **Yes**, a new protocol may be requested by the REB.

c) Will the proposed amendment affect the vulnerability of the participant group or the research risk?

☐ Yes ☒ No

If **Yes**, please indicate the **new** overall risk level on the Risk Matrix:

d) What follow-up action do you recommend for study participants who are already enrolled in the study?

- ☐ Inform study participants
- ☐ Revise consent/assent forms (please attach a copy with the changes)
- ☐ Other (please describe) Subject recruitment and exposure has not started yet

☒ No action required

4. RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY AND RESEARCH RISK

Information about how to use the risk matrix can be found on the following webpage: http://www.research.utoronto.ca/ethics/eh_forms.html. Please check one:

	Research Risk		
Group Vulnerability	**Low**	**Medium**	**High**
Low	1☒	1☐	2☐
Medium	1☐	2☐	3☐
High	2☐	3☐	3☐

Risk level = 1: Expedited Review **Risk level = 2 or 3: Full Review**

5. SIGNATURES

My signature certifies that the above information is correct and that no unapproved procedures will be used in this study.

Signature of Investigator: [redacted] Date: July 3, 2007

AND (if applicable)

Signature of Faculty Supervisor/Sponsor:
(for student or supervised research only) Date: